Claims:

1. A time-temperature indicator device for monitoring a therapeutic protein drug;
said indicator being associated with said drug throughout the majority of the drug's storage life;
said indicator having at least one time-temperature indication parameter selected by:
monitoring chemical and structural changes in the therapeutic protein as a function of time and storage temperature;
determining which time and temperature conditions cause a certain percentage of said protein to undergo structural or chemical alterations;
said percentage being set at a predetermined immunological risk threshold wherein amounts above said threshold have an unacceptable risk of provoking an immunological reaction;
said structural alterations being selected from the group consisting of protein aggregation, denaturation, dimerization, oxidation, deamidation, disulfide exchange, proteolysis, peptide map change, creation of antigenic activity, creation of antibody epitopes, or destruction of antibody epitopes;
Said immunological risk threshold being set at or below ten percent of the total quantity of said therapeutic protein.

2: The time-temperature indicator device of claim 1, in which the indicator is a chemically based time-temperature indicator with a visual display.

3: The time-temperature indicator device of claim 1, in which the indictor is an electronic time-temperature indicator with a visual display.

4: The time-temperature indicator device of claim 1, in which the therapeutic protein drug does not normally provoke an immune response, and in which the therapeutic drug is not a vaccine.

5: The time-temperature indicator device of claim 1, in which the indicator device contains computational means, and a temperature measurement means;
wherein said indicator periodically samples the temperature and computes a function of temperature that is continually operative throughout the relevant temperature monitoring range of the indicator;
and wherein said function of temperature approximates the impact that the relevant temperature, for that period's length of time, has on alterations in the structure or chemistry of said therapeutic protein;
and wherein said computing means generate a running sum of said function of temperature over time;
and wherein the granularity of the function of temperature is small enough, and the frequency of time measurements is often enough, as to substantially approximate the impact of time and temperature on the alterations in the structure or chemistry of said therapeutic protein;
and in which said running sum is compared to a reference value, and the result of said comparison is used to generate an output signal indicative of the fitness for use of said therapeutic protein.

6: The time-temperature indicator device of claim 1, in which the device additionally monitors parameters selected from the group consisting of motion, vibration, light, or turbidity, and adjusts its immunological risk threshold depending upon said additional parameters.

7. An electronic time-temperature indicator device for monitoring a non-vaccine therapeutic protein drug;
said indicator being associated with said drug throughout the majority of the drug's storage life;
said indicator having at least one time-temperature indication parameter selected by:
monitoring chemical and structural changes in the therapeutic protein as a function of time and storage temperature;

determining which time and temperature conditions cause a certain percentage of said protein to undergo structural or chemical alterations;
said percentage being set at a predetermined immunological risk threshold wherein amounts above said threshold have an unacceptable risk of provoking an immunological reaction;
said structural alterations being selected from the group consisting of protein aggregation, denaturation, dimerization, oxidation, deamidation, disulfide exchange, proteolysis, peptide map change, creation of antigenic activity, creation of antibody epitopes, or destruction of antibody epitopes;
said immunological risk threshold being set at or below ten percent of the total quantity of said therapeutic protein;
said indicator producing an output signal when said time-temperature indication parameters exceeds a preset limit.

8: The device of claim 7, in which the output signal is selected from the group consisting of visual output signals, vibration signals, sonic signals, radiofrequency signals, electrical signals, or infra-red signals.

9: The device of claim 7, further containing means to enable the time-temperature indication parameters to be automatically programmed into the assembled device.

10: The device of claim 7, in which the time-temperature indication parameters are computed by a microprocessor, the device is continually powered throughout its use lifetime, and the power means is selected from the group consisting of battery, storage capacitor, thermal, photoelectric, AC power, or radio frequency energy.

11: The device of claim 7, in which the device additionally conveys information selected from the group consisting of thermal history statistics, percentage of remaining lifetime, identification codes, and therapeutic protein prescribing information.

12: The time-temperature device of claim 7, incorporated into or interfaced with a therapeutic protein dispensing device, in which the time-temperature device signals if the therapeutic protein should be dispensed or not depending upon the acceptability of the material's thermal history.

13: The time-temperature indicator device of claim 7, in which the device additionally monitors parameters selected from the group consisting of motion, vibration, light, or turbidity, and adjusts its immunological risk threshold depending upon said additional parameters.

14: A method to determine the potential immunological risk of a therapeutic protein, said method comprising;
Constructing a pool of antibody or immune response genes representative of the genetic diversity of a target population;
Using said genetic pool to produce a panel of antibodies or immune response proteins directed against one or more representative samples of said therapeutic protein,
Using said panel to determine which epitopes are expressed on various preparations of said therapeutic proteins under various storage conditions;
said storage conditions representing at least different combinations of time and temperature storage parameters;
and determining what combinations of time and temperature storage parameters are associated with the formation of epitopes representative of immunogenic risk.

15: The method of claim 14, in which the panel of antibodies or immune response proteins is produced using methods selected from the group consisting of phage display, ribosome display, or lymphocyte antibody production methods.

16: The method of claim 14, used to optimize the structure, sequence, or chemical storage conditions of said therapeutic protein so as to minimize the chances of unwanted immunological activity with respect to said target population.

17: The method of claim 14, used as a method of manufacturing a drug compound, in which the method is used to optimize the drug structure to improve length of time and temperature that the drug may be stored before developing unwanted immunogenicity.

18: The method of claim 14, used to monitor the appearance of potentially immunogenic epitopes upon storage of a therapeutic protein.

19: The method of claim 14, used to determine optimal time-temperature storage conditions of a therapeutic protein.